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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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27777	7590	05/27/2004	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			ULM, JOHN D	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 05/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/875,456

Applicant(s)

QIN ET AL.

Examiner

John D. Ulm

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 14-16 and 18-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1646

1) Claims 1 to 34 are pending in the instant application. Claims 1 and 5 to 13 have been amended as requested by Applicant in the correspondence filed 18 March of 2004.

2) Claims 14 to 16 and 18 to 34 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 11, filed 23 December of 2002.

3) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5) Claims 11, 13 and 17 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. These claims encompass subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims for those reasons of record as applied to claims 1 to 3, 5 to 7, 9 to 13 and 17 in section 4 of the office action mailed 01 March of 2003. As stated therein, these claims require an isolated polynucleotide encoding a "Human β 1A sodium channel subunit" having other than the amino acid sequence presented in SEQ ID NO:14 of the instant application. No other "Human β 1A sodium channel subunit" is disclosed or suggested by the instant specification.

Art Unit: 1646

Applicant has traversed this rejection on the premise that the factors involved in determining if undue experimentation is required to practice the full scope of the claims have not been considered. Applicant's attention is directed to the original rejection, in which the lack of working examples, lack of guidance, and lack of predictability were all addressed. This rejection is maintained because Applicant has failed to identify any factual error in the original rejection. Applicant's argument that a protein of the instant invention shares certain structural features with a protein of the prior art does not avoid this rejection since the prior art also fails to provide the guidance needed to predictably alter the amino acid sequence of that protein. In those instances where a protein belongs to a family of proteins, such as the immunoglobulin family or the steroid/thyroid hormone receptor family, where a great deal of structure-function information is available from the prior art, one can make substantial alteration to that protein and predict, by resort to known scientific law, that the modified protein will, more likely than not, retained a desired function. In the instant case, however, there is no evidence that a protein of the instant invention belongs to such a well characterized family and, therefore, Applicant can not rely upon that which was known in the art to provide the guidance that is lacking from the instant specification.

Applicant alleges that the structural calculations presented in the original rejection are "contrary to Applicants' definition of a human β 1A sodium channel subunit protein and completely inconsistent with the claims read in view of the specification". Applicant has failed to identify any technical or mathematical error in the analysis of the original structural limitations presented in claim 1. With respect to the functional

Art Unit: 1646

limitations implied by the presence of the limitation "encodes a human β 1A sodium channel subunit protein", they do not inherently flow from the structural limitations originally recited therein.

Applicant urges that one can predict the function of a protein simply by observing a limited amino acid sequence similarity to a known protein. The fact that one can conclude that a specific protein belongs in a particular protein family based upon the fact that the amino acid sequence of the protein in question is at least 30% identical to a known member of that family conflicts in no way with the instant rejection. In fact, gross morphological structure alone is sufficient to establish a putative role for a newly discovered protein, in the absence of any significant identity to a known amino acid sequence. For example, the presence of seven transmembrane domains within the structure of a naturally occurring mammalian protein is generally sufficient to conclude that the protein is a receptor belonging to the G protein-coupled receptor family. However, being able to confidently assign a naturally occurring protein to an established protein family and being able to predictably alter the amino acid sequence of that protein are two entirely different issues. The instant rejection is based upon the fact that one can not predictably alter the single amino acid sequence presented in SEQ ID NO:14 of the instant specification because neither the instant specification nor the art of record provides the guidance to do so.

Applicant appears to have traversed this rejection on the premise that Applicant need not disclosed that which is well known. Obviously an isolated polynucleotide encoding a "Human β 1A sodium channel subunit" having other than the amino acid

Art Unit: 1646

sequence presented in SEQ ID NO:14 of the instant application is not well known in the art, as evidenced by the absence of an art rejection against claim 1 in the office action mailed 01 March of 2003.

6) Claims 1 to 13 and 17 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for those reasons of record in section 8 of the office action mailed 01 March of 2003.

6.1) Claims 1 to 13 and 17 are vague and indefinite in so far as they employ the term "Human β 1A sodium channel subunit" as a limitation. Because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a "Human β 1A sodium channel subunit" an artisan can not determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation. Applicant has traversed this rejection on the premise that the text on page 13 of the instant specification provides the required definition. The text relied upon by Applicant does not define the term "human β 1A sodium channel subunit". In fact the term "human β 1A sodium channel subunit" does not even appear on page 13 of the instant specification. The text referred to by Applicant does discuss a "human VGSC β 1A subunit". That text states that "[t]he present invention relates to DNA encoding human VGSC β 1A subunit that was isolated from human VGSC β 1A subunit producing cells" and that "[t]he term 'Human VGSC β 1A subunit' as used herein, refers to protein which can specifically function as a channel subunit", "[t]hat is, it can combine with the

Art Unit: 1646

other protein subunits to form a functioning calcium channel" (calcium channel???).

None of the features referred to by Applicant, such as a signal sequence, glycosylation sites, transmembrane domains, etc. are unique to a protein of the instant invention and none of these features, or any combination thereof are alleged to be unique to and definitive of a "human β 1A sodium channel subunit". These claims are vague and indefinite because an artisan can not distinguish between the subject matter encompassed by a claim to "an isolated polynucleotide encoding a human β 1A sodium channel subunit protein having the amino acid sequence of SEQ ID NO:14" and that of a claim to "an isolated polynucleotide encoding a protein having the amino acid sequence of SEQ ID NO:14".

6.2) Claim 1 is confusing because the preamble refers to "a sequence selected from the group consisting of" whereas the members of the group referred thereto are not sequences, they are polynucleotides. A polynucleotide is a material entity whereas a "sequence" is nothing more than a property such as color, shape and size. Claims 2 to 2 to 6 are indefinite in so far as they depend from claim 1 for this element.

6.3) Claims 5, 8 and 11 are vague and indefinite because the metes and bounds of the limitations "allelic variants" and "functional derivative" are undeterminable for those reasons of record in section 8.1 of the office action mailed 01 March of 2003. Applicant has traversed this rejection on the premise that the text on pages 23 and 24 of the instant specification provides the required definitions. A clear and unambiguous definition of either of these limitations is not provided by the text referred to by Applicant. That text essentially defines a "variant" as different, and an "allelic variant" as

Art Unit: 1646

naturally occurring and different. That text states that "[t]he term "functional derivatives" is intended to include the "fragments," "variants," "degenerate variants," "analogs" and "homologues" or to "chemical derivatives" of Human β 1A sodium channel subunit". A limitation that is defined in ambiguous terms is an ambiguous limitation. Claims 9 12 and 13 are indefinite in so far as they depend from any of claims 5, 8 are 11 for either of these elements.

7) Applicant's arguments filed 18 March of 2004 have been fully considered but they are not persuasive for those reasons given above.

8) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1646

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kunz Gary can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN ULM
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